DOCKET NO.: CRDS-0062 (CRD0931CIP) PATENT

**Application No.:** 10/829,074

Office Action Dated: November 6, 2006

This listing of claims will replace all prior versions, and listings, of claims in the application.

## **Listing of Claims:**

## 1-14. (canceled)

- 15. (Previously presented) A drug delivery device comprising: an intraluminal stent; a biocompatible, nonerodible polymeric coating affixed to the intraluminal stent; and rapamycin or a macrocyclic triene analog thereof that binds FKBP12 and is incorporated into the polymeric coating, wherein said device provides an in-stent late loss in diameter at 12 months following implantation in a human of less than about 0.5 mm, as measured by quantitative coronary angiography.
- 16. (Previously presented) A drug delivery device according to claim 15 that provides an in-stent late loss in diameter at 12 months following implantation in a human of less than about 0.3 mm, as measured by quantitative coronary angiography.
- 17. (Previously presented) A drug delivery device according to claim 15 or 16 that provides an in-stent diameter stenosis at 12 months following implantation in a human of less than about 22%, as measured by quantitative coronary angiography.
- 18. (Previously presented) A drug delivery device according to claim 17 that provides an in-stent diameter stenosis at 12 months following implantation in a human of less than about 15%, as measured by quantitative coronary angiography.
- 19. (Previously presented) A drug delivery device comprising: an intraluminal stent; a biocompatible, nonerodible polymeric coating affixed to the intraluminal stent; and rapamycin or a macrocyclic triene analog thereof that binds FKBP12 incorporated into the polymeric coating, wherein said device provides a mean in-stent late loss in diameter in a human population at 12 months following implantation of less than about 0.5 mm, as measured by quantitative coronary angiography.

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20. (Previously presented) A drug delivery device according to claim 19 that provides a mean in-stent late loss in diameter in a human population at 12 months following implantation of less than about 0.3 mm, as measured by quantitative coronary angiography.

- 21. (Previously presented) A drug delivery device according to claim 19 or 20 that provides a mean in-stent diameter stenosis in a human population at 12 months following implantation of less than about 22%, as measured by quantitative coronary angiography.
- 22. (Previously presented) A drug delivery device according to claim 21 that provides a mean in-stent diameter stenosis in a human population at 12 months following implantation of less than about 15%, as measured by quantitative coronary angiography.
- 23. (Previously presented) A method of inhibiting neointimal proliferation in a human coronary artery resulting from percutaneous transluminal coronary angioplasty comprising implanting in the lumen of said coronary artery a drug delivery device comprising: an intraluminal stent; a biocompatible, nonerodible polymeric coating affixed to the intraluminal stent; and rapamycin or a macrocyclic triene analog thereof that binds FKBP12 incorporated into the polymeric coating, wherein said method provides an in-stent late loss in diameter at 12 months following implantation of less than about 0.5 mm, as measured by quantitative coronary angiography.
- 24. (Previously presented) A method according to claim 23 that provides an in-stent late loss in diameter at 12 months following implantation of less than about 0.3 mm, as measured by quantitative coronary angiography.
- 25. (Previously presented) A method according to claim 23 or 24 that provides an instent diameter stenosis at 12 months following implantation of less than about 22%, as measured by quantitative coronary angiography.

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26. (Previously presented) A method according to claim 25 that provides an in-stent diameter stenosis at 12 months following implantation of less than about 15%, as measured by quantitative coronary angiography.

- 27. (Previously presented) A method of inhibiting neointimal proliferation in a coronary artery resulting from percutaneous transluminal coronary angioplasty comprising implanting in the lumen of said coronary artery a drug delivery device comprising: an intraluminal stent; a biocompatible, nonerodible polymeric coating affixed to the intraluminal stent; and rapamycin or a macrocyclic triene analog thereof that binds FKBP12 incorporated into the polymeric coating, wherein said method provides a mean in-stent late loss in diameter in a human population at 12 months following implantation of less than about 0.5 mm, as measured by quantitative coronary angiography.
- 28. (Previously presented) A method according to claim 27 that provides a mean instent late loss in diameter in a human population at 12 months following implantation of less than about 0.3 mm, as measured by quantitative coronary angiography.
- 29. (Previously presented) A method according to claim 27 or 28 that provides a mean in-stent diameter stenosis in a human population at 12 months following implantation of less than about 22%, as measured by quantitative coronary angiography.
- 30. (Previously presented) A method according to claim 29 that provides a mean in-stent diameter stenosis in a human population at 12 months following implantation of less than about 15%, as measured by quantitative coronary angiography.
- 31. (New) The drug delivery device according to any one of claims 15, 16, 18 or 19 wherein said rapamycin or macrocyclic triene analog thereof is incorporated into the polymeric coating at a dose of from about 64 μg to about 197 μg.

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32. (New) The drug delivery device according to claim 31 wherein said rapamycin or macrocyclic triene analog thereof is incorporated into the polymeric coating at a dose of from about 64  $\mu$ g to about 125  $\mu$ g.

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- 33. (New) The drug delivery device according to claim 31 that releases a portion of said dose of rapamycin or a macrocyclic triene analog thereof at about six weeks following intraluminal implantation.
- 34. (New) The drug delivery device according to any one of claims 15, 16, 18 or 19 wherein said rapamycin or macrocyclic triene analog thereof is incorporated into the polymeric coating at a dose of from about 2 µg to about 30 µg per millimeter of stent length.
- 35. (New) The drug delivery device according to claim 34 wherein said rapamycin or macrocyclic triene analog thereof is incorporated into the polymeric coating at a dose of from about 3 µg to about 13 µg per millimeter of stent length.
- 36. (New) The drug delivery device according to claim 34 that releases a portion of said dose of rapamycin or a macrocyclic triene analog thereof at about six weeks following intraluminal implantation.